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DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
FAX: (781) 279-1742

WARNING LETTER

NWE-14-01W

February 2, 2001

VIA FED EX

Ronald Messer, M. D.
South Shore Breast Evaluation Center
7 Driftway
Scituate, MA 02040

Dear Dr. Messer:

We are writing to you because on January 5, 2001, your facility was inspected by a representative of the Commonwealth of Massachusetts, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MSQA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings at your facility:

- Phantom QC records were missing for 7 weeks for unit 3, [redacted] in Mammo Room (R).

The specific problem noted above appeared on your MQSA Facility Inspection Report, which your facility received at the close of the inspection. This problem is identified as a repeat because it was cited as a Level 2 finding during the previous inspection of November 12, 1999, and indicates failure by your facility to implement permanent correction of problems found during your previous inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 (or repeated Level 3) findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 (or repeated Level 3) findings are:

- There is no written procedure for handling consumer complaints.
- Processor QC records were missing 2 consecutive days for processor 1, [redacted] in the darkroom.
- Mammograms were processed in processor 1, [redacted] in the darkroom when it was out of limits on 2 days.
- The fixer retention QC is not adequate for processor 1, [redacted] in that the fixer retention QC records were not done at the required frequency.

It is necessary for you to act on this matter immediately. Please explain to this office in writing with fifteen (15) working days from the date you received this letter.

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Michael J. Leal
MQSA Auditor
120 Front Street, Suite 680
Worcester, MA 01608

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P. O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. Leal at (508)793-0422.

Sincerely yours,

Gail T. Costello
District Director
New England District Office

[redacted]